

CLAIMS:

1. Method for determining the dosage of follicle-stimulating hormone (FSH) in the  
5 treatment of infertility of women comprising the determination of the FSH receptor  
variant of the woman to be treated.

2. The method of claim 1, wherein the determination of the FSH receptor variant  
comprises the steps:

- 10 (a) isolating genomic DNA from a blood sample of the woman to be treated, and  
(b) determining whether the isolated DNA codes for the FSH-receptor variant Ala  
307/Ser 680 or Thr 307/Asn 680.

3. The method of claim 2, wherein the determination of the FSH-receptor variant of  
15 step (b) is performed by —

- (b1) partial amplification of the FSH receptor DNA by use of a pair of primers flanking  
the variant region(s) of the FSH receptor DNA coding for the amino acids 307 and/or  
680 of the FSH receptor protein,  
(b2) digesting the amplified DNA with a restriction enzyme digesting only the DNA of  
20 one of the FSH receptor variants,  
(b3) determining the FSH-receptor variant by restriction fragment length-poly-  
morphism.

4. The method of claim 3, wherein the length of the primers is 12 to 30 nucleotides,  
25 preferably 17 to 25 nucleotides, and the distance to the nucleotides coding for the  
amino acid in positions 307 or 680 are 20 to 1500 bp, preferably 100 to 1000 bp.

5. The method of claim 3 ~~or 4~~, wherein the primers are flanking the DNA sequence of  
the amino acid in position 680 of the FSH receptor protein and the restriction enzyme  
30 is Bsr I.

00313491.121800

- a* 6. The method of ~~claims 3 to 5~~ <sup>claim 3</sup>, wherein the pair of primers comprises an upstream primer selected from

A<sub>1</sub>: 5'-GCTATACTGGATCTGAGATG

B<sub>1</sub>: 5'-TTGACATGACGTACACTGAG

- 5 C<sub>1</sub>: 5'-CTGATCTCTGCATTGGAATC

D<sub>1</sub>: 5'-AGCTGGACTGCAAGGTGCAG

E<sub>1</sub>: 5'-CCTTGTGCTCAATGTCCTGG

F<sub>1</sub>: 5'-CCATTTCTGCCTCCCTCAAG

G<sub>1</sub>: 5'-GAGCAAGTGTGGCTGCTATG,

- 10 and a reverse primer selected from

A<sub>2</sub>: 5'-ACCACTTCATTGCATAAGTC

B<sub>2</sub>: 5'-CAACTGATGCAATGAGCAGC

C<sub>2</sub>: 5'-ATCCAGCCCATCACCATGAC

D<sub>2</sub>: 5'-GGTTCCGCACTGTGAGGTAG

- 15 E<sub>2</sub>: 5'-GCTTTGGACACAGTGATGAG

F<sub>2</sub>: 5'-TGGATGGGTGTTGTGGACAG

G<sub>2</sub>: 5'-TGTAGAAGCACTGTCAGCTC,

preferably the pair of primers is E<sub>1</sub> and G<sub>2</sub> as defined above.

- 20 7. A method for treating infertility in women which comprises determining the FSH receptor variant in the woman to be treated as defined in ~~claims 1 to 6~~ <sup>claim 1</sup>.

8. The method of claim 7, further comprising administering the woman a suitable amount of FSH.

25

9. A kit for performing the determination of the FSH receptor variant in a woman as defined in ~~claims 1 to 8~~ <sup>claim 1</sup>.

*a*

*a* 10. The kit of claim 9 comprising a pair of primers as defined in ~~claims 3 to 6~~ <sup>claim 3</sup>, Taq polymerase and a restriction enzyme.

30

008121 16491 1660

11. A FSH preparation comprising a specific amount of FSH which is suitable as a daily dosage for high dosage, intermediate dosage or low dosage FSH treatment.

008727 1642660